REMARKS

I. Introduction

In response to the Office Action dated November 21, 2008, claim 32 has been amended. Claim 32 remains in the application. Re-examination and re-consideration of the application, as amended, is requested.

In response to the Notice of Non-Responsive Amendment dated September 1, 2009, a typographical error that present in claim 32 of the Amendment under 37 C.F.R. §1.111 filed with the Patent Office April 21, 2009 has been corrected. Applicants' attorney thanks the Examiner for pointing this out and apologizes for any inconvenience caused by this typographical error.

II. Amendments to the Specification

The specification has been amended hereinabove in accordance with the Examiner's suggestions. Trademarks are now delineated in accordance with the provisions of MPEP 608.01(v). In addition, the hyperlink has been deleted in accordance with the provisions of MPEP 608.01(p).

III. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments are fully supported by the specification as filed and introduce no matter. Methods directed to attracting T lymphocyte or mature host dendritic cells to a site of a spontaneous syngeneic tumor in a mammal are disclosed for example at page 17, lines 12-31 and in Example 4 at page 72.

IV. Rejection Under 35 U.S.C. § 101

In paragraphs (3) of the Office Action, claim 32 was rejected under 35 U.S.C. § 101 as not being supported by either a specific and substantial utility or a well established utility. This rejection is predicated on the belief that the utility encompassed by claim 32 requires the transplant of viable tumor cells into a human in order to establish a syngeneic tumor in the individual. In particular, at page 7, the Patent Office asserts that the claimed invention fails to meet the requirements of 35 U.S.C. § 101 because:

"The claimed process utilizes such syngeneic tumor models, but comprises introducing, not a polynucleotide encoding mSLC, but rather a polynucleotide encoding human secondary lymphoid tissue chemokine (hSLC) (i.e., a polypeptide having the amino acid sequence of SEQ ID NO: 1) into dendritic cells acquired from an individual mammal, and then reintroducing the recombinant dendritic cells expressing the polynucleotide at the site of an established syngeneic tumor in the individual.

It follows logically that **the claimed process will not be practiced using a human patient because it would be unethical, if not forbidden by law, to transplant viable tumor cells (syngeneic or otherwise) into a human** in order to establish a syngeneic tumor in the individual, so as to provide a model for the study of the effects of intratumoral injections of recombinant dendritic cells."

Applicants respectfully traverse this rejection because it fails to consider the utility of the claimed method when practiced on an individual suffering from a spontaneous syngeneic tumor, that is a tumor that arose spontaneously in a human (i.e. a cancer). While Applicants respectfully traverse this rejection, the claims have been amended hereinabove to recite methods directed to "attracting T lymphocyte or mature host dendritic cells to a site of a spontaneous syngeneic tumor in a mammal" in order to specifically exclude those methods that encompass the transplant of syngeneic cells into a human, (i.e. the methods that resulted in the above-noted rejection under 35 U.S.C. § 101). As noted for example at page 20, lines 24-28, because the spontaneous tumor models disclosed in the specification do not expose the animal's immune system to non-self antigens, do not mix cells and tissue from strains of mice that have been observed to have different immunological characteristics and is instead directed to evaluating an immune response to spontaneous tumors, the data provided by these models model is clinically relevant in the context of human cancers.

As noted above, the embodiments of the invention recited in claim 32 as amended hereinabove are now directed to attracting T lymphocyte or mature host dendritic cells to a site of a spontaneous syngeneic tumor in order to attract lymphocytes to the site of the tumor, an event that the specification teaches will reduce tumor burden. In particular, as described for example at page 12, lines 16-25, page 57, lines 2-21 and Example 4 at page 17 these methods will result in a reduction of tumor cells in the human mammal because the hSLC produced by the dendritic cells introduced

at the site of the tumor will chemo-attractively localize anti-tumor lymphocytes to the site of the spontaneous tumor.

In order to overcome the presumption of truth that an applicant enjoys when the utility of an invention is examined, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered "false' by a person of ordinary skill in the art. Moreover, as noted in M.P.E.P. §2107.02, where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong" even when there may be reason to believe that an assertion is not entirely accurate. Instead, an assertion of utility is to be considered credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Neither situation occurs in the utility associated with the method recited in claim 32 as amended hereinabove. Consequently, the legal presumption that Applicants statement of utility is true has not been overcome. For this reason, Applicants respectfully request a withdrawal of the rejection under 35 U.S.C. § 101.

V. Rejection Under 35 U.S.C. §112,

A. Rejection under 35 U.S.C. §112, first paragraph.

In paragraphs (8)-(9) of the Office Action, claim 32 was rejected under 35 U.S.C. §112, first paragraph.

In accordance with M.P.E.P. 2164.07, with the 35 U.S.C. §101 rejection, the Patent Office correspondingly asserts that because the claimed invention is not supported by either a specific, substantial and credible asserted utility, one skilled in the art clearly would not know how to use the claimed invention, and therefore this invention is not enabled (resulting in a rejection under 35 U.S.C. §112, first paragraph).

As noted above, claim 32 has been amended to specifically exclude those methods that encompass the transplant of syngeneic cancer cells into a human. A rejection to claim 32 as amended hereinabove is inconsistent with case law and PTO guidelines for making such rejections because, for example, there is no evidence to show that one of ordinary skill in the art would reasonably doubt the asserted utility. M.P.E.P. §2164.07 notes that Office personnel should not impose a 35

U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In this context, a factual showing must be provided if a 35 U.S.C. 112, first paragraph, rejection is to be imposed on "lack of utility" grounds. Specifically, M.P.E.P. §2164.07 states that only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant. As noted above, in the instant case, there is no evidence that one of ordinary skill in the art would reasonably doubt the asserted utility. Consequently, the rejection under 35 U.S.C. §112, first paragraph that is predicted on the utility rejection should therefore be withdrawn.

B. Rejection under 35 U.S.C. §112, second paragraph.

In paragraph (10)-(11) of the Office Action, claim 32 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have amended claim 32 in accordance with the Examiner's comments to overcome this rejection.

VI. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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